## REMARKS

Claims 19-31 are currently pending in the application. Claim 19 is withdrawn. Claims 1-18 were previously canceled as pertaining to a non-elected invention. Claims 20 and 31 are amended.

Claim 20 is amended to state that the apparatus is configured to drive the agent into a tissue wall. This is supported throughout the specification, namely at: page 3, lines 12-16; page 4, lines 17-21; page 4, line 27 to page 5, line 2; page 5, lines 11-17; page 5, lines 20-25; page 6, lines 10-17; page 8, lines 6-8; page 8, lines 16-18; page 10, lines 5-6; page 12, lines 2-3; page 12, lines 16-17; page 12, line 26 to page 13, line 1; page 13, lines 3-6; page 13, lines 14-16; page 16, lines 6-10; page 16, lines 23-24; page 17, lines 18-19; and page 18, lines 4-9.

New claim 32 recites that the port is formed from a convergence of a plurality of flexible fingers biased to hold at least one pellet. This is supported by Figs. 2A and 3A as originally filed and by the specification at page 11, lines 19-22 and page 12, lines 18-20.

No new matter is added.

Information Disclosure Statements

In addition to the references filed in parent patent application U.S. App. No. 08/993,586 (issued as U.S. Pat. No. 6,251,418), applicants also request consideration of the references in the Information Disclosure Statement filed herewith.

Claim Rejection Under 35 U.S.C. § 112, Second Paragraph

Claim 31 was rejected as indefinite on the grounds that the phrase "means for receiving at least one pellet" has not been described in the specification. Applicants note that claim 31 discloses "means for receiving at least one pellet containing the therapeutic agent and having an arcuate shape for facilitating implanting within a body of tissue", and that such steerable catheters capable of making arcuate bends are discussed in the specification, *e.g.*, from page 8, line 3 to page 10, line 13.

Applicants submit that claim 31 is clear on its face, and request that the rejection on this basis be reconsidered and withdrawn.

## APPLICANTS' INVENTION

Applicants' invention is an apparatus for implanting a therapeutic agent within a tissue wall. It includes an elongate flexible body, a delivery chamber coupled to the distal end and having a space for carrying the therapeutic agent, and a port for releasing the therapeutic agent. It also includes an actuator coupled to the delivery chamber and capable of driving the therapeutic agent through the port. The distal end is adapted to penetrate a tissue wall so that the therapeutic agent can be delivered and implanted within the tissue wall.

The apparatus can also include a control mechanism coupled to the actuator, which provides control of the actuator, and a steering mechanism for turning the distal end of the apparatus, allowing the user to selectively guide the device through a body lumen. It can also include a lever-action handle coupled to the control mechanism.

The distal end can be dimensionally adapted to allow for transluminal delivery entry into the interior of a patient's heart. It can also include a plunger for driving the therapeutic agent from the delivery chamber, such as a threaded plunger for advancing into the delivery chamber in response to a rotating action, and a ratchet assembly for allowing delivery of the therapeutic agent in discrete amounts.

The delivery chamber can be substantially cylindrical, and adapted to receive and store the therapeutic agent in the form of a pellet, for instance, a minisphere or a pellet having a pointed shape.

## THE CITED ART

### Lemelson (U.S. Pat. No. 4,588,395; "Lemelson")

U.S. Pat. No. 4,588,395 to Lemelson ("Lemelson") discloses a device for disposing material at a "select location" within the body. The material is retained within a housing which is located at the end of a flexible tube or catheter, which is inserted into a body cavity. The device is extended through a body lumen to the desired location, and the material is then expelled from the device by advancing a shaft.

There is no mention of the device being capable of implanting the material within a tissue wall.

**Matsuno *et al.* (U.S. Pat. No. 5,342,394; "Matsuno")**

U.S. Pat. No. 5,342,394 to Matsuno *et al.* ("Matsuno") discloses an apparatus for blocking the lumen of a vein branch that remains after a portion of the vein has been severed and used in a bypass operation elsewhere in the patient's body. The apparatus has an outer tube, an inner tube, a push-out member within the inner tube which pushes out a plug-like blocking member, which blocks the vein.

Matsuno makes no mention of implantation of a therapeutic agent or any kind of implantation within a tissue wall.

**Leschinsky *et al.* (U.S. Pat. No. 5,873,499; "Leschinsky")**

U.S. Pat. No. 5,873,499 to Leschinsky *et al.* ("Leschinsky") discloses a dispensing gun for dispensing a viscous fluid from a releasable dispenser, such as in a caulking gun. Leschinsky is not concerned with and does not disclose implantation of an agent within a tissue wall.

**Claim Rejections Under 35 U.S.C. § 102**

Claims 20-21, 23-26, 29 and 31 were rejected as anticipated by Lemelson. As stated in applicants' reply to the previous action, Lemelson does not anticipate the claims because it does not disclose that the device can be used to deposit the material into a tissue wall. Amended claim 20, in contrast, states that the apparatus is configured to drive the therapeutic agent into a tissue wall.

In response to applicants' previous arguments, the current action cited *In re Casey* (370 F.2d 576, 152 U.S.P.Q. 235 (C.C.P.A. 1967) and *In re Otto* (312 F.2d 937, 136 U.S.P.Q. 458 (C.C.P.A. 1963)) to support the statements that "a recitation of the intended use of the claimed invention must result in a structural difference between the claims invention and the prior art" and that "[i]f the prior art structure is capable of performing the intended use, then it meets the claim." However, amended claim 20 possesses exactly such a structural difference -- the claimed apparatus is configured to drive the agent into a tissue wall. Lemelson discloses no more than a device configured to cause the agent to either protrude from the end of the device, or to lie against tissue.

*Casey* and *Otto* are discussed in the Manual of Patent Examining Procedure (MPEP) at §§ 2111.02 and 2115. Section 2111.03 states that:

> During examination, statements in the preamble reciting the purpose or intended use of the claimed invention must be evaluated to determine whether the recited purpose or intended use results in a structural difference (or, in the case of process claims, manipulative difference) between the claimed invention and the prior art. If so, the recitation serves to limit the claim. See, e.g., *In re Otto*, 312 F.2d 937, 938, 136 USPQ 458, 459 (CCPA 1963) (The claims were directed to a core member for hair curlers and a process of making a core member for hair curlers. Court held that the intended use of hair curling was of no significance to the structure and process of making.)

Amended claim 20 states that the apparatus is configured to drive the agent into a tissue wall. The claimed apparatus is therefore structurally different from the Lemelson device.

MPEP § 2115 states that inclusion in the claim of the material or article worked upon does not limit apparatus claims. However, amended claim 20 requires that the apparatus is configured to drive an agent into a tissue wall. The Lemelson device is not configured in this way.

Applicants have amended claim 20 to state that the port and actuator are configured to drive the therapeutic agent into the tissue wall. In contrast, column 3, lines 37-42 of Lemelson clearly state that the flexible shaft pushes the material out, causing it to protrude from the end of the device, "or to eject it completely therefrom so that it lies against the tissue adjacent the end of the catheter" (emphasis added). Applicants have therefore made clear that the claims require that the apparatus do more than push out the agent. Rather, agent must be driven into tissue. This is throughout the specification. Furthermore, if applicants' claimed apparatus, as shown in Fig. 5 for example, were to eject the therapeutic agent as disclosed in Lemelson so that the agent lay against the myocardium, the agent would be swept away in the bloodstream, and would fail to be implanted within the tissue wall. This is discussed in the specification at page 13, lines 14-16, which discuss the formulation of the agent, and states that "[p]articles of this size are capable of providing a therapeutically effective dose of agent and can remain where implanted, resisting fluid flux through the tissue wall." (emphasis added).

Applicants' claims require that the apparatus be configured to drive the agent into a tissue wall. Lemelson contains no teaching or suggestion that the device disclosed therein is configured to drive the agent into tissue. This reference therefore cannot anticipate the claims, and the rejection on this basis must be reconsidered and withdrawn.

**Claim Rejections Under 35 U.S.C. § 103**

Claim 22 was rejected as unpatentable in view of Lemelson and Matsuno, and claims 27-28 and 30 were rejected as unpatentable in view of Lemelson and Leschinsky.

The addition of either Matsuno or Leschinsky does not cure the deficiency in Lemelson as discussed above. Like Lemelson, neither of Matsuno nor Leschinsky relates to or discloses implantation of a therapeutic agent within a tissue wall. Where none of the references relates to or discloses implantation of an agent into tissue, their combinations, even if proper (which is not conceded), cannot be considered to do so.

The § 103 rejection on this basis should be reconsidered and withdrawn.

Applicants submit that all of the claims are now in condition for allowance, which action is requested. Please apply any charges or credits to Deposit Account No. 50-1721.

Respectfully submitted,

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